

## PHARMACY BOARD[657]

### Notice of Intended Action

**Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”**

**Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.**

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The proposed amendments were approved at the August 31, 2016, regular meeting of the Board of Pharmacy.

The proposed amendments are intended to implement 2016 Iowa Acts, Senate File 2218, as amended by House File 2460, division XIV, which permits the possession and administration of opioid antagonist medications by certain eligible persons and allows the distribution of such medications by pharmacists pursuant to a standing order or collaborative agreement or pursuant to a prescription issued in the name of a law enforcement agency, fire department, or emergency medical service program. The amendments also remove the requirement for a pharmacy to include the address of a facility, school district, or accredited nonpublic school on the label of epinephrine dispensed to those entities.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 18, 2016. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to [terry.witkowski@iowa.gov](mailto:terry.witkowski@iowa.gov).

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement 2016 Iowa Acts, Senate File 2218, as amended by House File 2460, division XIV.

The following amendments are proposed.

ITEM 1. Amend subrule 8.19(1) as follows:

**8.19(1) Requirements for a prescription.** A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

*a. to d.* No change.

ITEM 2. Amend subrule 8.19(7) as follows:

**8.19(7) Epinephrine auto-injector prescription issued to school or facility.** A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

*a.* The pharmacy’s patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

*b.* The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall identify the name ~~and address~~ of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

ITEM 3. Adopt the following **new** subrule 8.19(8):

**8.19(8) Opioid antagonist prescription issued to law enforcement, fire department, or service program.** A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—8.31(135,147A). The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the law enforcement agency, fire department, or service program in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program to which the prescription was issued and the drug was dispensed.

b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

ITEM 4. Adopt the following **new** rule 657—8.31(135,147A):

**657—8.31(135,147A) Opioid antagonist dispensing by pharmacists by standing order.** An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's Web site, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or facility.

**8.31(1) Definitions.** For the purposes of this rule, the following definitions shall apply:

"*Authorized pharmacist*" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized Iowa-licensed pharmacist.

"*Department*" means the Iowa department of public health.

"*First responder*" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a fire fighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

"*Licensed health care professional*" means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

"*Opioid antagonist*" means the same as defined in Iowa Code section 147A.1 as amended by 2016 Iowa Acts, Senate File 2218.

"*Opioid-related overdose*" means the same as defined in Iowa Code section 147A.1 as amended by 2016 Iowa Acts, Senate File 2218.

"*Person in a position to assist*" means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.

"*Standing order*" means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

**8.31(2) Authorized pharmacist training and continuing education.** An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at

least one-hour duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order. An authorized pharmacist shall maintain competency by completing and maintaining documentation of completion of at least one hour of continuing education in opioid antagonist utilization every pharmacist license renewal period to continue eligibility to dispense opioid antagonists pursuant to a standing order.

**8.31(3) *Additional supply.*** Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the person in a position to assist.

**8.31(4) *Assessment.*** An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the person in a position to assist to receive and possess an opioid antagonist:

*a.* The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the person in a position to assist, including but not limited to a first responder or member of law enforcement.

*b.* The person in a position to assist is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

**8.31(5) *Person in a position to assist training and education.*** Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the person in a position to assist that includes, but is not limited to, the information identified in this subrule. An authorized pharmacist shall require the person in a position to assist to attest that, if the product will be accessible to any other individual for administration, the person in a position to assist will make available to such individual all received training and education materials. An authorized pharmacist may provide to the person in a position to assist written materials that include, but may not be limited to, the information identified in this subrule, but it shall not be in lieu of direct pharmacist consultation with the person in a position to assist.

*a.* The signs and symptoms of opioid-related overdose as described in the standing order.

*b.* The importance of calling 911 as soon as possible and the potential need for rescue breathing.

*c.* The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.

*d.* Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.

*e.* The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.

*f.* The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.

*g.* The prohibition of the person in a position to assist from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.

*h.* Information about substance abuse or behavioral health treatment programs.

**8.31(6) *Labeling.*** Upon the determination that a person in a position to assist is eligible to receive and possess an opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible person in a position to assist.

**8.31(7) *Reporting.*** A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

**8.31(8) *Records.*** An authorized pharmacist shall create and maintain an original record of each individual assessment, regardless of the eligibility determination following assessment, and dispensing

of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.